JAN 1 8 2005

K040625

1 of 3

510(K) SUMMARY

1. Submitter Name, Address, and Date of Submission:

Dr. Jack Atad
Director
Atad Developments and Medical Services Ltd.
70 Yakinton St.
Ramat Almogi
Haifa 34792, Israel

Telephone Number: (972) 48243342

Fax Number: (972) 48242662

E-Mail: atadjack@zahav.net.il

Contact: Same as above

2. Name of the Device, Common, Proprietary (if known), and Classification:

Classification Name: Hygroscopic Laminaria cervical dilator (21 C.F.R. § 884.4260)

Common Name: Cervical dilator
Proprietary Name: Atad Pre-Induction Cervical Dilator

3. Identification of the legally marketed device to which the submitter claims equivalence:

The Atad Pre-Induction Cervical Dilator (Atad Dilator) is substantially equivalent to the Quality Medical Solutions, LLC Laminaria Cervical Dilator, K021012, and other legally marketable laminaria indicated for cervical dilation.

4. Description of Device:

The Atad Dilator is an 18Fr, 400mm, natural latex, three-lumen, double latex balloon catheter with a corresponding valve for each balloon and a disabled third lumen that is not intended to be used.

5. Intended Use of the Device:

The Atad Dilator is indicated for mechanical dilation of the cervical canal prior to labor induction at term when the cervix is unfavorable for induction.

6. Summary of Technological Characteristics:

The Atad Dilator produces cervical dilation by the internal instillation of water in controlled spaces at the ends of the cervical canal. It is introduced through the lumen and expands the internal balloons. The operation is similar to laminaria which similarly expand internally within the canal through the absorption of water. The technological characteristics differ from those of a laminaria in terms of design, material and performance "mechanics." However, the design, materials and performance "mechanics" are comparable to marketed catheters and cannulas used for other purposes but which have exposure to the same body parts and locations. In particular, the Atad Dilator is comparable to the COOK Balloon Cannula and the COOK Double Balloon Hysterosalpingography Catheter (K890869).

The Atad Dilator, as with the laminaria, is inserted through the cervical canal and pressure is applied on the cervix by water-filled balloons inflated at the extremities of the cervix. This gradually will dilate the cervix in a period of approximately 6-12 hours. The predicate device laminaria is inserted through the cervical canal and is kept in place approximately 6-24 hours. By its hygroscopic capability, the expanded laminaria applies a gradual pressure on the cervix to effect its dilation. The Atad Dilator is inflated with 80 mL of sterile water or saline in each balloon. Following inflation of the two balloons positioned at the extremities of the cervix, pressure is applied on the cervix. The pressure applied by the balloons on the extremities of the cervix will dilate the cervix. Clinical trials support this effect in both the Atad Dilator and its predicate device, the laminaria. Cervical dilation of 3-4 cm occurs with the Atad Dilator.

Below is a table comparing the Atad Dilator atheter to the predicate laminaria:

FEATURE	**ATAD DILATOR**	**LAMINARIA**
Lithotomy position and insertion of a vaginal speculum in order to expose the cervix for the insertion of the Atad Dilator or laminaria:	Yes	Yes
Insertion through the cervical external os:	Yes	Yes
Prevention of cervical tears and fistula by gradual pressure on the cervix :	Yes	Yes
Gradual dilation of the cervix as a result of the pressure applied by the dilating mechanism:	Yes	Yes
No higher incidence of preterm labor or late abortions following the procedure:	True	True
Time required to achieve dilation:	6-12 hrs.	6-24 hrs.
Effectiveness of the method:	Comparable	Comparable
Safety:	Comparable	Comparable
Mean insertion to delivery time (Hours):	19-25	6-23
Cesarean delivery range (%):	13% -28%	20% - 40%
Increased risk to the outcome of pregnancy	None	None
Vaginal packing required to avoid expulsion and displacement	Not required	Required
Difficulties in removal of the laminaria or the Atad Dilator	Not recorded	Possible
Need of lithotomy and vaginal speculum insertion for removal	No need	Needed

7. Summary of Non-Clinical and Clinical Tests and How Results Support Substantial Equivalence

The Atad Dilator has been subjected to all appropriate biocompatibility and performance testing including burst, pressure and flow rate testing. The device was found acceptable in all non-clinical testing phases. The safety and effectiveness of the Atad Dilator for cervical dilation prior to labor induction in women at term has been demonstrated in several clinical trials.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 18 2005

Atad Developments and Medical Services Ltd.
c/o Mr. Neil F. O'Flaherty
Olsson, Frank and Weeda, P.C.
1400 Sixteenth Street, NW, Suite 400
WASHINGTON D.C. 20036

Re: K040625
Trade/Device Name: Atad Pre-Induction Cervical Dilator
Regulation Number: 21 CFR 884.4260
Regulation Name: Hygroscopic-laminaria cervical dilator
Regulatory Class: II
Product Code: 85 HDY
Dated: October 20, 2004
Received: October 20, 2004

Dear Mr. O'Flaherty:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K040625

Device Name: Atad Pre-Induction Cervical Dilator

Indications for Use: The Atad Pre-Induction Cervical Dilator is indicated for mechanical dilation of the cervical canal prior to labor induction at term when the cervix is unfavorable for induction.

Prescription Use __X__ **AND/OR** **Over-The-Counter Use** _____
(Part 21 CFR 801 Subpart D)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K040625